HFV- 305 (Dockets)

AUG 10 1999

DATE OF APPROVAL LETTER:

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-095

DECTOMAX® (doramectin)

0.5% Pour-On Solution for Cattle

"...for treatment and control of *Trichostrongylus axei* (L_4)"

"...control infection and to protect cattle from reinfection with *Haemonchus placei* for 35 days after treatment"

Sponsored by:

Pfizer, Inc.

I. GENERAL INFORMATION: NADA NO. 141-095

Sponsor:	Pfizer, Inc 235 East 42nd Street New York, New York 10017
Established Name:	doramectin
Trade Name:	DECTOMAX® (doramectin) Pour-On
Marketing Status:	over-the-counter (OTC)
Effect of Supplement:	New indications for therapeutic efficacy against *Trichostrongylus axei* (L_4) and persistent efficacy for 35 days against *Haemonchus placei*.

II. INDICATIONS FOR USE: For the treatment and control of the following in cattle.

Gastrointestinal roundworms	*Ostertagia ostertagi*	Adults and fourth-stage larvae
	Ostertagia ostertagi	Inhibited fourth-stage larvae
	Ostertagia lyrata	Adults
	Haemonchus placei	Adults and fourth-stage larvae
	Trichostrongylus axei	Adults and fourth stage larvae
	Trichostrongylus colubriformis	Adults and fourth-stage larvae
	Cooperia oncophora	Adults and fourth-stage larvae
	Cooperia punctata	Adults and fourth-stage larvae
	Cooperia pectinata	Adults
	Cooperia surnabada (syn. mcmasteri)	Adults
	Bunostomum phlebotomum	Adults
	Oesophagostomum radiatum	Adults and fourth-stage larvae
	Trichuris spp.	Adults
Lungworms	*Dictyocaulus viviparus*	Adults and fourth-stage larvae
Eyeworms	*Thelazia gulosa*	Adults
	Thelazia skrjabini	Adults
Grubs	*Hypoderma bovis*	
	Hypoderma lineatum	
Lice	Sucking *Haematopinus eurysternus*	Biting *Damalinia bovis*
	Linognathus vituli	
	Solenopotes capillatus	
Mange mites	*Chorioptes bovis*	
	Sarcoptes scabiei	
Horn Flies	*Haematobia irritans*	

Dectomax pour-on solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, *Ostertagia ostertagi*, *Cooperia punctata,* and *Oesophagostomum radiatum* for 28 days after treatment, and *Haemonchus placei* for 35 days after treatment.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE:

A. Dosage Form: Pour-on solution containing 5 mg doramectin/mL.

B. Route of Administration: DECTOMAX® (doramectin) Pour-On should be applied topically along the mid-line of the back.

C. Approved Dose: 500 mcg doramectin/kg body weight (5 mL/110 lb body weight)

IV. EFFECTIVENESS:

Data demonstrating the effectiveness of DECTOMAX® (doramectin) Pour-On for previously registered indications are discussed in the parent NADA 141-095 FOI Summary (approval date September 16, 1997). Data from the following dose confirmation trials demonstrate that the efficacy of DECTOMAX® (doramectin) Pour-On, administered at the recommended dosage treats and controls *Trichostrongylus axei* (L4) and controls infections and prevents reinfection with *Haemonchus placei* for up to 35 days after treatment.

TRICHOSTRONGYLUS AXEI (L_4) THERAPEUTIC EFFECTIVENESS

SUMMARY

Two dose confirmation studies (1231C-60-93-017, 1231C-60-97-278) were conducted to confirm the effectiveness of doramectin pour-on, administered topically at a dose of 500 mcg/kg, against *Trichostrongylus axei* L_4 infections in cattle.

RESULTS

Results are presented on an individual study basis in the section following (see Tables 4.1 and 4.2).

OVERALL CONCLUSIONS

A single topical application of doramectin pour-on at a dosage of 500 mcg/kg was highly efficacious in reducing *Trichostrongylus axei* L_4 recovered at necropsy from calves artificially infected with infective larvae of *Trichostrongylus axei.*

A. Dose Confirmation Study 1231C-60-93-017

1. Investigator: Dr. L.R. Ballweber
College of Veterinary Medicine
Mississippi State University
Mississippi State, Mississippi

2. General Design:

   a. Purpose: To evaluate the therapeutic efficacy of doramectin pour-on at a dosage of 500 mcg/kg BW against artificially-induced, immature nematode infections in cattle.

   b. Animals: Ten (10) per group. Animals were 5 to 6 months old and weighed 125 to 191 kg at the start of the study.

   c. Controls: Animals in the negative control group (T1) received no medication.

   d. Procedure: On Day 0, calves were weighed and randomly allocated to a non-medicated group or a doramectin-treated group. All calves received infective larvae of *Trichostrongylus axei* on Day 11. On Day 17, animals in the doramectin group (T2) were treated topically with doramectin pour-on at a dose of 500 mcg/kg BW. Animals in group T1 received no medication. Animals were euthanized and necropsied on Days 31 and 32 for determination of worm burdens.

3. Results: The percentage reduction in arithmetic mean nematodes in the doramectin group, compared to the non-medicated group, is summarized in Table 4.1. There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

   Table 4.1: Percent efficacy of doramectin pour-on solution administered topically at 500 mcg/kg

Parasite	Arithmetic Mean Worm Counts		% Efficacy
	Non-medicated	Doramectin	
Trichostrongylus axei L4	640	0	100

4. Data analysis: Total *Trichostrongylus axei* L_4 burdens for each animal were estimated from the number of fourth-stage larval parasites found in the abomasum at necropsy.

   Arithmetic mean nematode counts were calculated for each nematode species. These were used to estimate the percentage efficacy for the treated group compared to the non-medicated group using the following formula:

[(Arithmetic mean number of worms in non-medicated cattle) - (Arithmetic mean number of worms in doramectin-treated cattle)] ÷ [Arithmetic mean number of worms in non-medicated cattle] X 100 = Percentage Efficacy

5. Conclusion: A single application of doramectin pour-on administered to cattle at a dose of 500 mcg/kg BW was effective against induced *Trichostrongylus axei* L4 infection in cattle.

B. Dose Confirmation Study 1231C-60-97-278

1. Investigator: Edward G. Johnson
   24007 Highway 20/26
   Parma, Idaho

2. General Design:

   a. Purpose: To evaluate the therapeutic efficacy of doramectin pour-on at a dosage of 500 mcg/kg BW against artificially-induced infections of immature stages of *Trichostrongylus axei* infections in cattle.

   b. Animals: Ten (10) per group. Animals were 3 to 6 months old and weighed 119 to 217 kg at the start of the study.

   c. Controls: Animals in the control group (T1) received saline.

   d. Procedure: Calves were randomly allocated to a non-medicated group or a doramectin-treated group. All calves received infective larvae of *Trichostrongylus axei* on Day 0. On Day 10, calves were weighed and animals in the doramectin group (T2) were treated topically with doramectin pour-on at a dose of 500 mcg/kg BW. Animals in group T1 received saline at a dose of 1 mL/10 kg BW. Animals were euthanized and necropsied on Day 21 for determination of worm burdens.

3. Results: The percentage reduction in arithmetic mean nematodes in the doramectin group, compared to the non-medicated group, is summarized in Table 4.2. There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

Table 4.2. Percent efficacy of doramectin pour-on solution administered topically at 500 mcg/kg

Parasite	Arithmetic Mean Worm Counts		% Efficacy
	Non-medicated	Doramectin	
Trichostrongylus axei L4	5490	0	100

4. Data analysis: Arithmetic mean worm counts were calculated for worm species. These were used to estimate the percentage efficacy for the treated group compared to the non-medicated group, using the following formula:

   [(Arithmetic mean number of nematodes in non-medicated cattle) - (Arithmetic mean number of nematodes in doramectin-treated cattle)] ÷ [Arithmetic mean number of nematodes in non-medicated cattle] X 100 = Percentage Efficacy

5. Conclusion: A single application of doramectin pour-on administered to cattle at a dose of 500 mcg/kg BW was effective against induced *Trichostrongylus axei* L4 infection in cattle.

PERSISTENT EFFICACY - *HAEMONCHUS PLACEI*

SUMMARY

Two dose confirmation studies (1231C-60-95-199, 1231C-60-97-277) were conducted to evaluate the persistent efficacy of doramectin pour-on, administered topically at a dose of 500 mcg/kg against artificial infections of nematodes.

RESULTS

Results are presented on an individual study basis in the section following (see Tables 4.3 and 4.4).

OVERALL CONCLUSIONS

A single topical application of doramectin pour-on at a dosage of 500 mcg/ provided persistent efficacy against challenge infections of *Haemonchus placei* for up to 35 days after treatment. No significant adverse reaction to treatment was observed in either study.

A. Dose Confirmation Study 1231C-60-95-199

1. Investigator: Edward G. Johnson
   24007 Highway 20/26
   Parma, Idaho

2. General Design:

   a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg BW against artificially induced nematode infections.

   b. Animals: Ten (10) per group. Animals were 4 to 6 months old and weighed 127 to 251 kg at the start of the study.

   c. Controls: Animals in the negative control group (T1) received saline.

   d. Procedure: Forty-two (42) animals were weighed and randomly allotted to a saline-treated group (T1, 10 animals) or to one of three doramectin-treated groups (T2 to T4, 10 animals each) on Day 0. No physical contact was permitted between groups. On Day 0, animals in Groups T1 and T2 were treated topically with saline (1 mL/10 kg BW) or doramectin pour-on (500 mcg/kg BW), respectively. Groups T3 and T4 were treated with doramectin pour-on in an identical manner on Days 7 and 14, respectively.

   All animals in Groups T1 to T4 were challenged daily on Days 14 to 35 with infective *Haemonchus placei* larvae (1995 mixed strain isolated in Louisiana and Idaho). Animals from Groups T1 to T4 were euthanized and necropsied on Days 49 and 50 for determination of worm counts.

3. Results: The percentage reduction in geometric mean nematodes in the doramectin group, compared to the non-medicated group, is summarized in Table 4.3. There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

Table 4.3: Geometric Mean *Haemonchus placei* Nematode Counts and Percent Efficacy

Treatment	Group Size	Persistence Interval	Mean Worm Counts	% Efficacy
T1 - Saline	10	--	106	--
T2 - Doramectin	10	35 days	3	97.4
T3 - Doramectin	10	28 days	0	100
T4 - Doramectin	10	21 days	0	100

4. Data analysis: Nematode percentage efficacy was calculated using the following formula:

   [(Geometric mean number of worms in non-medicated cattle) - (Geometric mean number of worms in doramectin-treated cattle)] ÷ [Geometric mean number of worms in non-medicated cattle] X 100 = Percentage Efficacy

5. Conclusion: A single application of doramectin pour-on administered to cattle topically at a dose of 500 mcg/kg BW provided persistent efficacy against challenge infections of *Haemonchus placei* for 35 days.

B. Dose Confirmation Study 1231C-60-97-277

1. Investigator: Edward G. Johnson
   24007 Highway 20/26
   Parma, Idaho

2. General Design:

   a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg BW against artificially induced nematode infections.

   b. Animals: Ten (10) per group. Animals were 5 to 6 months old and weighed 113 to 263 kg at the start of the study.

   c. Controls: Animals in the control group (T1) received saline.

   d. Procedure: Forty-two (42) animals were weighed and randomly allotted to a saline-treated group (T1, 10 animals), to one of three doramectin-treated groups (T2 to T4, 10 animals each), or as larval monitors (2 animals) on Day 0. No physical contact was permitted between groups.

      On Day 0, animals in Groups T1 and T2 were treated topically with saline (1 mL/10 kg BW) or doramectin pour-on (500 mcg/kg BW), respectively. Groups T3 and T4 were treated with doramectin pour-on in an identical manner on Days 7 and 14, respectively.

      All animals in Groups T1 to T4 were challenged daily on Days 21 to 35 with infective *Haemonchus placei* larvae (1997 strain isolated in Mississippi). The two larval viability monitor animals were challenged on Day 35, to confirm the viability of the inoculum at the end of the infection phase of the study. Animals from Groups T1 to T4, and larval monitor animals were euthanized and necropsied on Day 49 for determination of worm counts.

3. Results: The percentage reduction in geometric mean nematodes in the doramectin group, compared to the non-medicated group, is summarized in table 4.4. There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

Table 4.4. Geometric Mean *Haemonchus placei* Nematode Counts and Percent Efficacy

Treatment	Persistence Interval	Mean Worm Counts	% Efficacy
T1 - Saline	--	368	--
T2 - Doramectin	35 days	4	98.9
T3 - Doramectin	28 days	10	97.2
T4 - Doramectin	21 days	1	99.6

4. Data analysis: Geometric mean worm counts were calculated for worm counts. These were used to estimate the percentage efficacy for the treated group compared to the non-medicated group, using the following formula:

   [(Geometric mean number of nematodes in non-medicated cattle) - (Geometric mean number of nematodes in doramectin-treated cattle)] ÷ [Geometric mean number of nematodes in non-medicated cattle] X 100 = Percentage Efficacy

5. Conclusion: A single application of doramectin pour-on administered to cattle topically at a dose of 500 mcg/kg BW provided persistent efficacy against challenge infections of *Haemonchus placei* for 35 days.

V. ANIMAL SAFETY:

As discussed in the parent NADA 141-095 FOI Summary (approval date Sept. 16, 1997).

VI. HUMAN SAFETY

As discussed in the parent NADA 141-095 FOI Summary (approval date Sept. 16, 1997) and supplemental approval FOI Summary (dated October 25, 1998).

VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) to demonstrate that DECTOMAX® (doramectin) Pour-On, is safe and effective for the treatment and control of *Trichostrongylus axei* (L_4) in cattle and to control infections and to protect cattle from re-infection with *Haemonchus placei* for 35 days after treatment, when administered topically at a dose of 500 mcg/kg bodyweight.

There are no changes to the codified tolerances for doramectin in cattle or to the established preslaughter withdrawal time of 45 days.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(ii) of the FFDCA, this approval for food producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

DECTOMAX® (doramectin) Pour-On is under U.S. patent number 5,089,480, which expires on July 30, 2010.

VIII. APPROVED PRODUCT LABELING (attached)

A. Facsimile label - 250 mL, 1 liter, 2.5 liter, and 5 liter containers

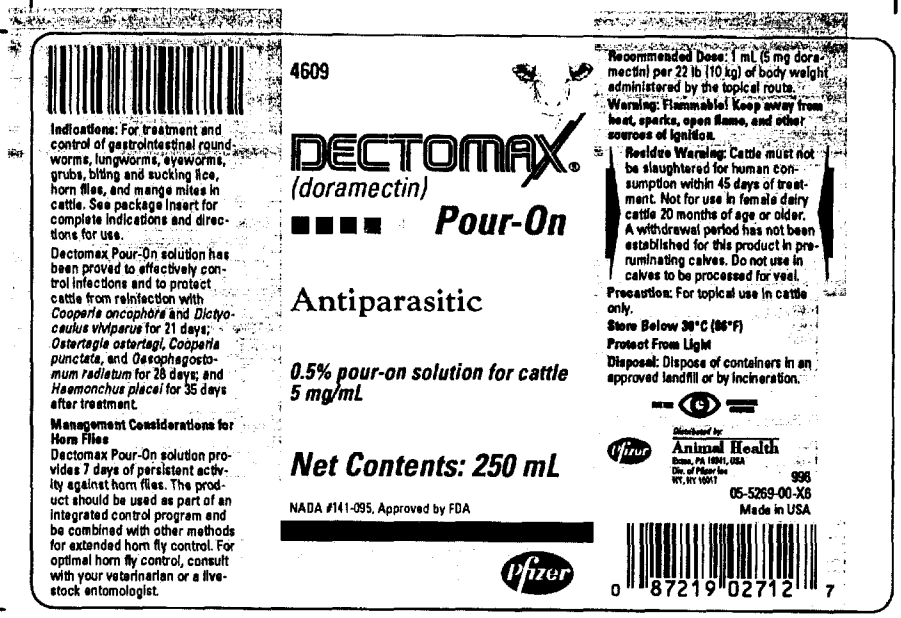
B. Facsimile package insert.

C. Box carton – 250 mL size

cc:
Courtesy Copy for the Sponsor
HFV-199/N-141095-C-0011
HFV-2 (Special Mailing List)
HFV-15 (FOI Staff)
HFV-102 (GADQC Reserve Copy)
HFV-102 (GREEN BOOK)
HFV-135 (Messenheimer)
HFA-305 (Dockets Management Branch)
HFR-SW350 (KAN-DO)

HFV-135:JRMessenheimer:6/30/99:827-7578

ec: CVM Records:\ONADE\\N141095\C0011foi.sum



Code 128:

055269003

4 1/2" (W) x 3" (H)

				PATTERN VARNISH
PMS 116	10, 20, 40, 60, 80, 100% Reflex Blue	Black	60% Black	

05-5269-00-X6 Draft #1 6/23/99

4610

DECTOMAX®

(doramectin)

Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 1 liter

NADA #141-095, Approved by FDA

Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days; *Ostertagia ostertagi, Cooperia punctata,* and *Oesophagostomum radiatum* for 28 days; and *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight administered by the topical route.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Precaution: For topical use in cattle only.

Store Below 30°C (86°F)

Protect From Light

Disposal: Dispose of containers in an approved landfill or by incineration.

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

996
05-5271-00-X6
Made in USA

0 87219 02714 1

Code 128:

055271002

5" (W) x 5" (H)

PMS 116	10, 20, 40, 60, 80, 100% Reflex Blue	Black	60% Black	PATTERN VARNISH

05-5271-00-X6 Draft #1 6/23/99

4611

Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days; *Ostertagia ostertagi, Cooperia punctata,* and *Oesophagostomum radiatum* for 28 days; and *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight administered by the topical route.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Precaution: For topical use in cattle only.

Store Below 30°C (86°F)

Protect From Light

Disposal: Dispose of containers in an approved landfill or by incineration.

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

996
05-5273-00-X6
Made in USA

0 87219 02716 5

DECTOMAX®
(doramectin)

Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 2.5 liters

NADA #141-095, Approved by FDA

Pfizer

Code 128:

055273002

5" (W) x 5 1/2" (H)

PMS 116	10, 20, 40, 60, 80, 100% Reflex Blue	Black	60% Black	PATTERN VARNISH

05-5273-00-X6 Draft #1 6/23/99

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4612

DECTOMAX®

(doramectin)

■■■■ Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 5 liters

NADA #141-095, Approved by FDA

[redacted]

Pfizer

Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days; *Ostertagia ostertagi, Cooperia punctata,* and *Oesophagostomum radiatum* for 28 days; and *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight administered by the topical route.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Precaution: For topical use in cattle only.

Store Below 30°C (86°F)

Protect From Light

Disposal: Dispose of containers in an approved landfill or by incineration.

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

996
05-5275-00-X6
Made in USA

0 87219 02718 9

Code 128:

055275002

6 1/2" (W) x 7 3/16" (H)

PMS 116	10, 20, 40, 60, 80, 100% Reflex Blue	Black	60% Black	Pattern Varnish

05-5275-00-X6 Draft #1 6/23/99

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Code 128: 105269002

Die # 257C

4 7/16" x 2 9/16" x 7 7/8"

PMS 116	11, 22, 30, 33, 44, 55, 66, 77, 100% Reflex blue	Black	60% Black	PATTERN VARNISH

Carton Visual Code Bar: 9

10-5269-00-X6 Draft #1 6/23/99

65%

0000010

Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days; *Ostertagia ostertagi*, *Cooperia punctata*, and *Dictyocaulus radiatum* for 28 days; and *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies

Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Warning: Flammable! Keep away from heat, sparks, open flames, and other sources of ignition.

Dectomax Pour-On solution for cattle may be irritating to human skin and eyes, and users should be careful not to apply it to themselves or to other persons. Operators should wear protective clothing including a long-sleeved shirt, rubber gloves, and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention. Wash hands after use. Do not smoke or eat while handling the product.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Precautions: This product is to be applied to skin surface only. Do not administer orally or parenterally. Do not apply to areas of skin which are caked with mud or manure.

Use Conditions: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

Store Below 30°C (86°F).

Protect from Light.

Dispose: Dispose of containers in an approved landfill or by incineration.

Animal Health
Exton, PA 19341, USA
A unit of Pfizer Inc
NADA 141-095

10-5269-00-X6
Made in USA

DECTOMAX®
Pour-On

DECTOMAX®
Pour-On

DECTOMAX®
Pour-On

4609

DECTOMAX®
(doramectin)
Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Treats 10 550-lb cattle

Net Contents: 250 mL

NADA #141-095, Approved by FDA

Pfizer

Dosage and Administration: Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:

Body Weight (lb)	Dose (mL)
Up to 110	5 mL*
111–220	10 mL
221–330	15 mL
331–440	20 mL
441–550	25 mL
551–660	30 mL
661–770	35 mL
771–880	40 mL
881–990	45 mL
991–1100	50 mL

* Administer using an appropriate dosing gun.

For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1–110 lb of body weight.

0 87219 02712 7

DECTOMAX®

(doramectin)

Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

PRODUCT DESCRIPTION: Dectomax Pour-On solution is a ready-to-use, systemically active, clear, light blue solution containing 0.5% w/v doramectin (5 mg/mL). It is formulated to deliver the recommended dosage of 500 mcg/kg (227 mcg/lb) of body weight when given by topical administration at the rate of 1 mL/22 lb (10 kg) of body weight.

PRODUCT CHARACTERISTICS: Dectomax Pour-On solution is a highly active, broad-spectrum parasiticide for topical administration to cattle. It contains doramectin, a novel fermentation-derived macrocyclic lactone discovered by Pfizer Inc. Doramectin is isolated from fermentations of selected strains derived from the soil organism *Streptomyces avermitilis*.

A primary mode of action of macrocyclic lactones is to modulate chloride ion channel activity in the nervous system of nematodes and arthropods. Macrocyclic lactones bind to receptors that increase membrane permeability to chloride ions. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods and causes paralysis and death of the parasites. In mammals, the neuronal receptors to which macrocyclic lactones bind are localized within the central nervous system (CNS), a site reached by only negligible concentrations of doramectin.

One dose of Dectomax Pour-On solution effectively treats and controls a wide range of roundworm and arthropod parasites that impair the health and productivity of cattle.

Studies have demonstrated the safety margin of doramectin. In USA trials, no toxic signs were seen in cattle given up to 25 times the recommended dose of Dectomax Injectable solution. A study using Dectomax Injectable solution also demonstrated safety in neonatal calves treated with up to 3 times the recommended dose. In breeding animals (bulls, and cows during folliculogenesis, organogenesis, implantation, and through gestation), a dose 3 times the recommended dose of Dectomax Injectable solution had no effect on breeding performance. A pharmacokinetic study demonstrated that systemic exposure to doramectin from Dectomax Pour-On was less than systemic exposure to doramectin from Dectomax Injectable solution.

PRODUCT INDICATIONS: Dectomax Pour-On solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs (see PRECAUTIONS), biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal roundworms
- *Ostertagia ostertagi* (adults and L_4, including inhibited larvae)
- *O. lyrata* (adults)
- *Haemonchus placei* (adults and L_4)
- *Trichostrongylus axei* (adults and L_4)
- *T. colubriformis* (adults and L_4)
- *Cooperia oncophora* (adults[1] and L_4)
- *C. pectinata* (adults)
- *C. punctata* (adults and L_4)
- *C. surnabada* (adults)
- *Bunostomum phlebotomum* (adults)
- *Oesophagostomum radiatum* (adults and L_4)
- *Trichuris* spp. (adults)

[1] Efficacy below 90% was observed against adult *C. oncophora* in some clinical studies.

Lungworms (adults and fourth stage larvae)
- *Dictyocaulus viviparus*

Eyeworms
- *Thelazia gulosa* (adults)
- *T. skrjabini* (adults)

Grubs
- *Hypoderma bovis*
- *H. lineatum*

Lice
- Biting Lice
  - *Damalinia bovis*
- Sucking Lice
  - *Haematopinus eurysternus*
  - *Linognathus vituli*
  - *Solenopotes capillatus*

Horn Flies
- *Haematobia irritans*

Mange Mites
- *Chorioptes bovis*
- *Sarcoptes scabiei*

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days; *Ostertagia ostertagi*, *Cooperia punctata*, and *Oesophagostomum radiatum* for 28 days; and *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

DOSAGE: Administer Dectomax Pour-On solution to cattle topically at a dosage of 500 mcg doramectin per kg (227 mcg/lb) of body weight. Each mL contains 5 mg of doramectin, sufficient to treat 22 lb (10 kg) of body weight.

For the best results, Dectomax Pour-On solution should be a part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult a veterinarian or an entomologist for information regarding the most effective timing of applications.

ADMINISTRATION: Dectomax Pour-On solution should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

Dosing Cup (250-mL and 1-L bottles)

A dosing cup is provided for use with Dectomax Pour-On solution supplied in 250-mL and 1-L bottles. The Dectomax Pour-On solution dosing cup should be installed by rotating the cup on the bottle neck until tight. When installed correctly, the spout is aligned at the mid-point on the wide side of the bottle.

The curved end of the dosing cup tube should be positioned at the bottom of the bottle on the side opposite the spout. When the dosing cup is in the closed position ("zero" at set dosage mark on screw), product does not enter the cup reservoir. Select a dose (1 mL per 22 lb (10 kg) of body weight) by twisting the dosing screw on the top of the dosing cup to the desired position. The first complete turn of the dosing screw will set the dose at 10 mL ("10" shows on the screw at set dose mark). Each additional turn increases the dose in 5 mL increments until a maximum dose of 50 mL ("50" is the bottom number showing on screw at the set dose mark) is reached. When body weight is between weight markings on the dosing cup, use the higher dose volume.

To fill the dosing reservoir, hold the bottle upright and squeeze it until a slight excess has been delivered as indicated by the calibration lines. Release the pressure and excess will automatically drain from the reservoir and return to the bottle.

Tilt the bottle to deliver the dose. Dectomax Pour-On solution should be delivered to cattle on the back in a single pass from the withers to the tailhead.

[redacted]

Black 60% Black (on icon)

Code 128:

695269002
2" (W) x 15" (H)

Folds to: 2" x 1"
Visual Code Bars: 0,1,2,7,8

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Applicators (2.5-L and 5-L bottles)
Applicators are available for use with Dectomax Pour-On solution supplied in 2.5- and 5-L backpacks. Directions for 2 recommended applicators are provided below. Some applicators may be incompatible with this formulation.

Phillips Pour-on Applicator System
1. Replace the shipping cap on 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring counter clockwise over the tubing and draw-off spigot.
3. Invert the backpack.
4. Set the dose to maximum (50 mL). Gently prime the applicator, checking for leaks. To prime, place the nozzle into a clean, dry receptacle and depress lever fully. Pump 3–4 short strokes ensuring that the piston reaches the end of the cylinder, and then release the lever completely to fill the cylinder. A small air bubble may appear within the cylinder. This will not affect the dosing accuracy.
5. Set the required dose and administer.
6. To disconnect the system, proceed as follows:
   a) Set backpack in upward position.
   b) Discharge residual material from the applicator and draw-off tubing into a separate, clean, dry receptacle.
7. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.
8. Remove the draw-off cap. Replace with the original cap and tighten firmly.

Syvret Pour-on Applicator System
1. Replace the shipping cap on the 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring clockwise over the tubing and draw-off spigot.
3. Invert the backpack.
4. Set the dose at the maximum (50 mL) by unscrewing the adjuster at the base of the handle. Gently prime the applicator, checking for leaks. To prime, point the nozzle into a clean, dry receptacle and gently pump the lever back and forth to expel air from the system. When the barrel completely fills after every priming stroke, set the dose.
5. Set the dose as follows:
   a) Use the handle to align the middle of the blue plunger ring with the chosen mark on the barrel. Tighten the adjuster screw against the handle.
   b) Secure the dose with the adjuster screw locknut.

Note: Dose accuracy can be checked by dispensing a known number of set doses into a measuring cylinder. Correct any inaccuracy by adjusting the dose setting screw. Repeat this procedure until desired accuracy is achieved.
6. Administer each dose by fully depressing the handle so that the plunger travels its entire set length. Release the handle and the applicator will automatically refill.
7. To disconnect the system proceed as follows:
   a) Set backpack in upward position.
   b) Discharge residual material from the applicator and draw off tubing into a separate, dry receptacle.
8. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.
9. Remove the draw-off cap. Replace with the original cap and tighten firmly.

WARNING: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition. Not for human use. Keep out of reach of children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain an MSDS, call 1-800-366-5288.

Dectomax Pour-On solution for cattle may be irritating to human skin and eyes, and users should be careful not to apply it to themselves or to other persons. Operators should wear protective clothing including a long-sleeved shirt, rubber gloves, and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

RESIDUE WARNING: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS:
This product is to be applied to skin surface only. Do not administer orally or parenterally.

Do not apply to areas of skin which are caked with mud or manure.

Wash hands after use.

Do not smoke or eat while handling the product.

Cloudiness in the formulation may occur when Dectomax Pour-On solution is stored at temperatures below 0°C (32°F). Allowing to warm to room temperature will restore the normal appearance without affecting efficacy.

Dectomax Pour-On solution is highly effective against cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble) season.

Destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *H. lineatum* when it is in the tissue surrounding the gullet may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Dectomax Pour-On solution, but can occur with any successful treatment of grubs. Cattle should be treated either before or after the migratory phase of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Dectomax Pour-On solution after the end of heel fly season may be re-treated with Dectomax Pour-On during the winter for internal parasites, mange mites, or biting and sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

Use Conditions: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

Caution: Dectomax Pour-On solution has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

ENVIRONMENTAL SAFETY: Studies indicate that when doramectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free doramectin may adversely affect fish or certain waterborne organisms on which they feed. Do not permit cattle to enter lakes, streams or ponds for at least 6 hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Store Below 30°C (86°F)

Protect From Light

HOW SUPPLIED: Dectomax Pour-On solution is available in 250-mL, 1-L, 2.5-L, and 5-L multi-dose containers.

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